

Notice of Allowability

Application No.

10/031,516

Applicant(s)

SCHAFFAR, BERHARD PETER
HARALD

Examiner

Susan Hanley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 7/12/04.
2. ☒ The allowed claim(s) is/are 10-22.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

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Specification

The substitute specification filed 7/12/04 has not been entered because a substitute specification was not required by Examiner in the Office Action of 1/4/04. The objection to the specification only required the insertion of appropriate section headings, as specified by 37 CFR 1.77(b). The headings will be inserted by Examiner's amendment.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

In the specification, the heading -- **Background of the Invention** -- was inserted in the line between the title, "CREATINE BIOSENSORS" and the first line of text beginning with, "This invention relates to...". The heading -- **Summary of the Invention** -- was inserted between the last line of section [009] and the first line of section [0010]. The heading -- **Detailed Description of the Invention** -- was inserted between the last line of section [0011] and the first line of section [0012].

The following is an examiner's statement of reasons for allowance: The instant invention is novel and unobvious over Monbouquette (US 6,241,863). Monbouquette discloses several methods of making amperometric biosensors. In one method, one or more enzymes can be deposited upon an electrode having an amphiphilic lipid already deposited on the surface of the electrode followed by cross-linking of the enzymes. In another method, one or more enzymes can be combined with an amphiphilic lipid and then deposited upon an electrode. The deposition of the mixture is followed by cross-linking of the enzymes. These two methods are claimed in claimed 1-13. These methods differ from the instantly

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claimed method in that the enzyme that is combined with an amphiphilic substance is cross-linked to the electrode and there is no further deposition of layers of enzyme(s). Nor is there a suggestion to do so.

Monbouquette also teaches that a population of enzymes can be cross-linked and then deposited onto a lipophilic layer. No further layering is described nor suggested. This method is claimed in claims 17-19 and the result is depicted in Figure 13.

Monbouquette also describes a method of layering enzymes on an electrode surface that requires cross-linking in all of the layering steps (col. 13, lines 1-55). This prior art method differs from the instantly claimed method in that the enzyme/surfactant layer that is initially deposited on the electrode is cross-linked to the electrode. The instant method does not require cross-linking of the deposited enzyme on the electrode. Nor does the instant method require that the next layer of enzyme is chemically immobilized "thereupon" which is interpreted to mean that the next layer is connected to the first layer and not the electrode.

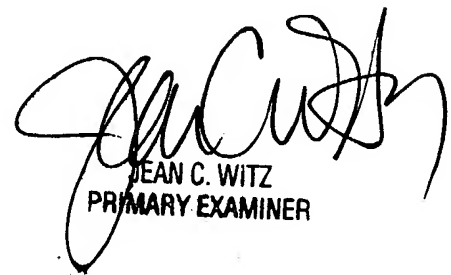
Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Hanley whose telephone number is 571-272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



JEAN C. WITZ
PRIMARY EXAMINER